requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 28, 1995.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(d) is amended in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(d) * * *

Inert ingredient	Limits	Uses
* *	* * *	* *
Cellulose acetate (CAS Reg. No. 9004-35-7), minimum number average molecular weight 28,000.	.....	Pesticide rate-release regulating agent.
* *	* * *	* *

* * * * *

[FR Doc. 95–26061 Filed 10–24–95; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 180

[PP 4F4391/R2180; FRL–4982–8]

RIN 2070–AB78

Pyrithiobac Sodium Salt; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a time-limited tolerance, to expire on September 30, 1997, for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on the raw agricultural commodity cottonseed at 0.02 part per million (ppm). E.I. du Pont de Nemours & Co., Inc., submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) requesting the regulation to establish a maximum permissible level for residues of the herbicide in or on the commodity.

EFFECTIVE DATE: This regulation becomes effective October 25, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP4F4391/R2180], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM 1B2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 4F4391/R2180]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Theresa A. Stowe, Acting Product Manager (PM 22), Registration Division (7505C), Office of Pesticide Programs, Enviromental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm.

229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6117; e-mail: stowe.theresa@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the Federal Register of June 15, 1995 (60 FR 31466), which announced that E. I. du Pont de Nemours Co., Inc., Barley Mill Plaza, Walker's Mill, P.O. Box 80038, Wilmington, DE 19880-0038, had submitted a pesticide petition, PP 4F4391, to EPA requesting that the Administrator, pursuant to section 408(d) of the FFDCA (21 U.S.C. 346a(d)), amend 40 CFR part 180 by establishing a regulation to permit residues of pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on the raw agricultural commodity cottonseed at 0.02 part per million (ppm).

There were no comments or requests for referral to an advisory committee received in response to the notice of filing.

The scientific data submitted in the petition and all other relevant material have been evaluated. The toxicology data considered in support of the tolerance include the following:

1. A rat acute oral study with a LD_{50} of 3,300 milligrams (mg)/kilogram (kg) for males and a LD_{50} of 3,200 mg/kg for females.

2. A 90-day rat feeding study with a no-observed-effect level (NOEL) of 500 ppm (31.8 mg/kg/day for males and 40.5 mg/kg/day for females) and a lowest-observed-effect level (LOEL) of 7,000 ppm (466 m/kg/day for males and 58.8 mg/kg/day for females), based on decrease body weight gains and increased rate of hepatic B-oxidation in males.

3. A 90-day mouse feeding study with a NOEL of 500 ppm (83.1 mg/kg/day for males and 112 mg/kg/day for females) and a LOEL of 1,500 ppm (263 mg/kg/day for males and 384 mg/kg/day for females) based on increased liver weight and an increased incidence of hepatocellular hypertrophy in males and decreased neutrophil count in females.

4. A 3-month dog feeding study with a NOEL of 5,000 ppm (165 mg/kg/day) and a LOEL of 20,000 ppm (626 mg/kg/day), based on decrease red blood cell count, hemoglobin, and hematocrit in females and increased liver weight in both sexes.

5. A 21-day rat dermal study with a dermal irritation NOEL of 50 mg/kg/day and a dermal irritation LOEL of 500 mg/kg/day based on increased incidence of erythema and edema, and with a systemic dermal NOEL of 500 mg/kg/day and a systemic dermal LOEL of 1,200 mg/kg/day based on body weight gain inhibition.

6. A 90-day rat neurotoxicity screening battery with a systemic NOEL of 7,000 ppm (466 mg/kg/day for males and 588 mg/kg/day for females) and a systemic LOEL of 20,000 ppm (1,376 mg/kg/day for males and 1,609 mg/kg/day for females), based on decreased hind grip strength and increased foot spay in males, and a neurotoxicity NOEL of 20,000 ppm [highest dose tested (HDT)].

7. A 78-week dietary carcinogenicity study in mice with a NOEL of 1,500 ppm [217 mg/kg/day (males) and 319 mg/kg/day (females)] and a LOEL of 5,000 ppm [745 mg/kg/day (males) and 1,101 m/kg/day (females)] based on decreased body weight/gain in both sexes, treatment related increase in the incidence of foci/focus of hepatocellular alternation in males, and increased incidence of glomerulonephropathy [murine] in both sexes, and an increased incidence of infarct in the kidney and keratopathy of the eyes in 1.43 mg/kg/day and a LOEL of 28.6 mg/kg/day (males) and 92.9 mg/kg/day (females) based on hepatocellular enlargement and a greater incidence and severity of hepatocellular vacuolation. There was evidence of carcinogenicity based on significant differences in the pair-wise comparisons of the liver tumors in the 150 and 1,500 dose groups (but not at the high dose of 5,000 ppm). The carcinogenic effects observed are discussed below.

8. A 24-month rat chronic feeding/carcinogenicity study with a systemic NOEL of 1,500 ppm (58.7 mg/kg/day) for males and 5,000 ppm (278 mg/kg/day) for females and a systemic LOEL of 5,000 ppm (200 mg/kg/day) for males and 1,500 ppm (918 mg/kg/day) for females based on decreases in body weight, body weight gains and food efficiency in females, increased incidence of eye lesions in males and females, mild changes in hematology and urinalysis in both sexes, clinical signs suggestive of urinary tract dysfunction in males and females, increased incidence of focal cystic degeneration in the liver and renal tubular adenomas and adenocarcinomas in males, increased rate of hepatic peroxisomal B-oxidation in males and an increased incidence of inflammatory, degenerative, and neoplastic microscopic lesions in the kidney in females. There was evidence of carcinogenicity based on the increasing trend in kidney tubular combined adenoma/carcinoma in male rats and an increasing trend in kidney tubular bilateral and/or unilateral adenomas in females. The carcinogenic effects observed are discussed further below.

9. A 1-year dog chronic feeding study with a NOEL of 5,000 ppm (143 mg/kg/day for males and 166 mg/kg/day for females) and a LOEL of 20,000 ppm (580 mg/kg/day for males and 647 mg/kg/day for females) based on decreases in body weight gain and increased liver weight.

10. A two generation reproduction study in rats with a maternal NOEL of 1,500 ppm (103 mg/kg/day) and a maternal LOEL of 7,500 ppm (508 mg/kg/day ppm), based on decreased body weight/gain and food efficacy. The reproductive and offspring NOEL is 7,500 ppm (508 mg/kg/day) and the reproductive and offspring LOEL is 20,000 ppm (1,551 mg/kg/day), based on decreased pup body weight.

11. A developmental toxicity study in rabbits with a maternal and developmental NOEL of 300 mg/kg and a maternal LOEL of 1,000 mg/kg based on deaths, decreased body weight gain and feed consumption, increased incidence of clinical signs, and an increase in early resorptions and a developmental LOEL of 1,000 mg/kg, based on decreased fetal body weight gain.

12. A developmental toxicity study in rats with a maternal NOEL 200 mg/kg and a maternal LOEL of 600 mg/kg due to increased incidence of salivation. The developmental NOEL is 600 mg/kg and the developmental LOEL is 1,800 mg/kg based on the increased incidence of skeletal variations .

13. No evidence of gene mutation was observed in a test for induction of forward mutations at the HGPRT locus in Chinese hamster ovary cells. No evidence was observed for inducing reverse gene mutation in two independent assays with *Salmonella typhimurium* with and without mammalian metabolic activation. Pyrithiobac-sodium was negative for the induction of micronuclei in the bone marrow cells of mice, and negative for induction of unscheduled DNA synthesis in rat primary hepatocytes. Pyrithiobac-sodium was positive for inducing chromosome aberrations assay in human lymphocytes.

14. A rat metabolism study showed that radiolabeled pyrithiobac-sodium is excreted in urine and feces with greater than 90 percent being eliminated within 48 hours. A sex difference was observed in the excretion and biotransformation. Females excreted a greater amount of the radiolabel in the urine than males following all dosing regimens, with a corresponding lower amount being eliminated in the feces compared to the males.

The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of pyrithiobac sodium salt in mice and rats and has classified pyrithiobac sodium salt as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the Federal Register in 1986 (51 FR 33992, Sept. 24, 1986) and recommended that for the purpose of risk characterization a low-dose extrapolation model should be applied to the experimental animal tumor data for quantification for human risk ($Q1^*$). This decision was based on liver adenomas, carcinomas and combined adenoma/carcinomas in the male mouse and rare kidney tubular adenomas, carcinomas and combined adenoma/carcinomas in male rat. The unit risk, $Q1^*$ $(mg/kg/day)^{-1}$, of pyrithiobac- sodium is 1.05×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents based on male kidney tumors.

Based on assumption that 100% of the crop is treated with pyrithiobac-sodium, the upper-bound limit of the dietary carcinogenic risk is calculated in the range of 1 incidence in a billion (1.0×10^{-9}).

Processing studies for cotton have shown that pyrithiobac-sodium does not concentrate in cottonseed processed commodities. Therefore, food/feed additive tolerances are not needed in conjunction with these uses.

Using the NOEL of 58.7 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100-fold safety factor, the Reference Dose (RfD) for systemic effects is 0.58 mg/kg/day. The theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.000001 mg/kg/day and utilizes less than 1 percent of the RfD for the overall U.S. population. For exposure of the most highly exposed subgroup in the population, children aged 1 through 6 years of age, the TMRC is 0.000001 mg/kg/day, which is still less than 1 percent of the RfD.

The metabolism of pyrithiobac-sodium in plants is adequately understood. Due to the following chemistry data gap, Magnitude of Residue Data for cotton gin byproducts [GLN 171-4], EPA believes it is inappropriate to establish permanent tolerances for the uses of pyrithiobac-sodium at this time. However, since the pesticide labeling accepted under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), as amended, bears a restriction against feeding cotton gin byproducts from treated fields to livestock, EPA believes that the existing data support time-limited tolerances to September 30, 1997.

The nature of the residue in plants is adequately understood for the purposes of these time-limited tolerances. An analytical method, high- pressure liquid chromatography, is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the Pesticide Analytical Manual, Vol. II (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to any one interested in pesticide enforcement when requested from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-5232).

There is no reasonable expectation that secondary residues will occur in milk, eggs or meat of livestock and poultry since, due to the label restriction against feeding cotton gin byproducts from treated fields to livestock, there are no livestock feed items associated with this action. The pesticide is considered useful for the purpose for which the tolerance is sought.

Based on the information and data considered, the Agency has determined that the amending of 40 CFR part 180 will be safe. Therefore, the regulation is established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 4F4391/R2180) (including any objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall 1B2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the document control number [PP 4F4391/R2180], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:
opp@docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all objections and hearing requests submitted directly in writing. The official rulemaking record is the paper record maintained at the address in ''ADDRESSES'' at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f),

the order defines a ''significant regulatory action'' as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not ''significant'' and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 29, 1995.

Penelope A. Fenner-Crisp,

Deputy Director, Office of Pesticide Programs.

Therefore, title 40 of the Code of Federal Regulations is amended in part 180 as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By adding new § 180.487, to read as follows:

§ 180.487 Pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate); tolerances for residues.

A time-limited tolerance is established for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on the following raw agricultural commodity:

Commodity	Parts per million	Expiration date
Cottonseed	0.02	Sept. 30, 1997.

[FR Doc. 95–26472 Filed 10–24–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Parts 185 and 186

[FAP 3H5678/R2176; FRL–4980–1]

RIN 2070–AB78

Tralomethrin; Food and Feed Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes food/feed additive regulations for the combined residues of the pyrethroid tralomethrin and its metabolites *cis*-deltamethrin and *trans*-deltamethrin in or on food and feed items as a result of the application of this pesticide in food/feed handling establishments. The regulation to establish maximum permissible levels for residues of the pesticide in food/feed as a result of application of this insecticide in food/feed handling establishments was requested in a petition submitted by AgrEvo Environmental Health (formerly Roussel UCLAF Corp.).

EFFECTIVE DATE: This regulation becomes effective October 25, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [FAP 3H5678/R2176], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [FAP 3H5678/R2176]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: George T. LaRocca, Product Manager (PM) 13, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 204, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6100; e-mail: larocca.george@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of October 21, 1993 (58 FR 54356), which announced that AgrEvo Environmental Health had submitted a food/feed additive petition (FAP) 3H5678 to EPA requesting that the Administrator, pursuant to section 409(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 348(e), amend 40 CFR parts 185 and 186 by establishing a food/feed additive regulation to permit residues of the synthetic pyrethroid tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl] cyclopropanecarboxylate) and its metabolites *cis*-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] and *trans*-deltamethrin [(*S*)-*alpha*-cyano-3-phenoxybenzyl (1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate] in or on food and feed as a result of use in food/feed-handling establishments at 0.02 part per million (ppm). Treatments may be made by general surface, spot, and/or crack and crevice application.

There were no comments received in response to the notice of filing. The scientific data submitted in support of the food and feed additive regulations and other relevant material have been evaluated. The toxicological data considered in support of these regulations are discussed in detail in